

**UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE**

<b>UNITED STATES OF AMERICA,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Case No. 2:19-cv-00009</b>
	)	
<b>OAKLEY PHARMACY, INC., et al.,</b>	)	<b>Judge Trauger</b>
	)	
<b>Defendants.</b>	)	

**DEFENDANT MICHAEL GRIFFITH’S ANSWER TO COMPLAINT FOR  
DECLARATORY AND INJUNCTIVE RELIEF AND CIVIL MONETARY PENALTIES  
UNDER THE CONTROLLED SUBSTANCES ACT, AND FOR  
FALSE CLAIMS ACT RELIEF**

Defendant Michael Griffith hereby responds to the Complaint for Declaratory and Injunctive Relief and Civil Monetary Penalties Under the Controlled Substances Act, and for False Claims Act Relief [Doc. No. 1] filed by the United States as follows:

1. Mr. Griffith admits that paragraph 1 accurately reflects the allegations brought by the United States but denies that he has committed any violations of law or is liable to the United States for any alleged violations.

**INTRODUCTION<sup>1</sup>**

2. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 2 and thus denies the allegations.

3. Mr. Griffith denies the allegations contained in paragraph 3.

4. Mr. Griffith admits that paragraph 4 accurately reflects the relief sought by the United States but denies that he has committed any violations of law and that the United States is entitled to the relief sought.

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<sup>1</sup> The headings from the Complaint [Doc. No. 1] are included throughout for ease of reference and require no response.

5. Mr. Griffith admits that paragraph 5 accurately reflects the relief sought by the United States but denies that he has committed any violations of law and that the United States is entitled to the relief sought.

#### **JURISDICTION AND VENUE**

6. Mr. Griffith admits the allegations contained in paragraph 6.

7. Mr. Griffith admits that venue in the Middle District of Tennessee is proper but denies that he has committed any violations of law and that the United States is entitled to the relief sought.

8. Mr. Griffith admits the allegations contained in paragraph 8, upon information and belief.

9. Mr. Griffith admits the allegations contained in paragraph 9, upon information and belief.

10. Mr. Griffith admits the allegations contained in paragraph 10, upon information and belief.

11. Mr. Griffith admits the allegations contained in the first and second sentences of paragraph 11, upon information and belief. The third sentence of paragraph 11 contains legal conclusions to which no response is required.

12. Mr. Griffith admits the allegations contained in the first sentence of paragraph 12, upon information and belief. As to the allegations in the second sentence of paragraph 12, the statutory provision cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the language of that provision. The third sentence of paragraph 12 contains legal conclusions to which no response is required.

13. Mr. Griffith admits the allegations contained in the first and fourth sentences of paragraph 13. As to the allegations in the second sentence of paragraph 13, the statutory provision cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the language of that provision. The third sentence of paragraph 13 contains a legal conclusion to which no response is required.

14. Mr. Griffith admits the allegations contained in first, second, and fourth sentences of paragraph 14, upon information and belief. The third sentence of paragraph 14 contains a legal conclusion to which no response is required.

15. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 15 and thus denies the allegations. Mr. Griffith further states that the articles cited speak for themselves and denies any allegation to the extent it is inconsistent with the content of the articles.

16. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 16 and thus denies the allegations. Mr. Griffith further states that the articles cited speak for themselves and denies any allegation to the extent it is inconsistent with the content of the articles.

17. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 17 and thus denies the allegations.

18. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 18 and thus denies the allegations.

19. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 19 and thus denies the allegations.

20. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 20 and thus denies the allegations.

21. Mr. Griffith admits the allegations contained in the first and second sentences of paragraph 21. As to the allegations in the third sentence of paragraph 21, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language. Mr. Griffith further states that the statute cited applies to physicians, not to pharmacists.

22. Mr. Griffith is without sufficient information to admit or deny the allegations contained in the first, second, and fourth sentences of paragraph 22 and thus denies the allegations. As to the allegations in the third sentence of paragraph 22, the guidelines cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the language of the cited authority. Mr. Griffith further states that the guidelines cited apply to physicians, not to pharmacists.

23. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 23 and thus denies the allegations.

24. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 24 and thus denies the allegations. Mr. Griffith further states that the articles cited speak for themselves and denies any allegation to the extent it is inconsistent with the content of the articles.

25. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 25 and thus denies the allegations. Mr. Griffith further states that the articles cited speak for themselves and denies any allegation to the extent it is inconsistent with the content of the articles.

26. Mr. Griffith denies the allegations contained in paragraph 26.

27. Mr. Griffith admits the allegations contained in the first sentence of paragraph 27. Mr. Griffith is without sufficient information to admit or deny the allegations contained in the second sentence of paragraph 27 and thus denies the allegations. As to the allegations contained in the third sentence of paragraph 27, the statutory provision cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the language of that provision.

28. Mr. Griffith admits the allegations contained in paragraph 28.

29. As to the allegations in paragraph 29, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

30. As to the allegations in paragraph 30, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

31. As to the allegations in paragraph 31, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

32. As to the allegations in paragraph 32, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

33. As to the allegations in paragraph 33, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

34. As to the allegations in paragraph 34, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

35. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 35 and thus denies the allegations.

36. Mr. Griffith admits the allegations contained in paragraph 36.

37. As to the allegations in paragraph 37, the statutes cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory language.

38. As to the allegations in paragraph 38, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

39. As to the allegations in paragraph 39, the statute and regulation cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory or regulatory language.

40. As to the allegations in paragraph 40, the statutes cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory language.

41. As to the allegations in paragraph 41, the statute and regulation cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory or regulatory language.

42. As to the allegations in paragraph 42, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language.

43. As to the allegations in the first sentence of paragraph 43, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language. The second sentence of paragraph 43 contains a legal conclusion to which no response is required. Mr. Griffith further denies that he knowingly filled any controlled substance prescriptions not issued for a legitimate medication purpose and any allegation that he had a duty not to do so.

44. As to the allegations in paragraph 44, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language.

45. Mr. Griffith denies the allegations contained in paragraph 45.

46. As to the allegations in paragraph 46, the regulations cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory language. The allegation further contains a legal conclusion to which no response is required.

47. Mr. Griffith denies the allegations contained in paragraph 47.

### **The False Claims Act**

48. As to the allegations in paragraph 48, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

49. As to the allegations in paragraph 49, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

50. As to the allegations in paragraph 50, the statute and regulation cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory or regulatory language. Mr. Griffith further denies that he is liable to the United States for either damages or civil penalties.

### **The Medicare Program**

51. As to the allegations in paragraph 51, the statutes cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory language.

52. Mr. Griffith admits the allegations in the first sentence of paragraph 52. The allegations contained in the second sentence contain a legal conclusion to which no response is required.

53. As to the allegations in paragraph 53, the statutes and regulations cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the statutory or regulatory language.

54. Mr. Griffith admits the allegations contained in paragraph 54.

55. As to the allegations in paragraph 55, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further denies that the regulation cited applies to him and that he violated any laws or regulations.

▪ **Part D Plan Sponsors Submit Prescription Drug Events for Drugs Covered Under Medicare Part D**

56. Mr. Griffith denies the allegations contained in paragraph 56.

57. Mr. Griffith admits the allegations contained in paragraph 57, upon information and belief.

58. Mr. Griffith admits the allegations contained in paragraph 58, upon information and belief.

59. As to the allegations in paragraph 59, the instructions cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the language of the cited instructions.

▪ **CMS Makes Three Types of Payments to Part D Plan Sponsors**

60. Mr. Griffith admits the allegations contained in paragraph 60.

61. As to the allegations in paragraph 61, the regulations cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further denies that the regulations cited apply to him and that he violated any laws or regulations.

62. As to the allegations in paragraph 62, the regulations cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further denies that the regulations cited apply to him and that he violated any laws or regulations.

63. As to the allegations in paragraph 63, the regulations and instructions cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further denies that the regulations cited apply to him and that he violated any laws or regulations.

64. Mr. Griffith admits the allegations contained in paragraph 64.



▪ **Plan D Sponsors and Their Contractors Certify Compliance with All Applicable Federal Laws, Regulations and CMS Instructions**

65. Mr. Griffith admits the allegations contained in paragraph 65, but denies that he is a Part D Plan Sponsor and further denies that he failed to comply with any applicable laws, regulations, or instructions.

66. As to the allegations in paragraph 66, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language. Mr. Griffith further denies that the statute cited applies to him and that he violated any laws or regulations.

67. As to the allegations in paragraph 67, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith denies that the regulation cited stands for the proposition contained in paragraph 67. Mr. Griffith further denies that the regulation cited applies to him and that he violated any laws or regulations.

68. As to the allegations in paragraph 68, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further denies that the regulation cited applies to him and that he violated any laws or regulations.

69. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 69 and thus denies the allegations.

70. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 70 and thus denies the allegations.

71. As to the allegations in paragraph 71, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language.

72. As to the allegations in paragraph 72, the regulations cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further

denies that the regulation cited includes the language “true, accurate, and complete” as a condition of payment to Part D plan sponsors, as is alleged in paragraph 72.

73. As to the allegations in paragraph 73, the regulations and statutes cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory or statutory language. Mr. Griffith further denies that the regulations and statutes cited apply to him and that he violated any laws or regulations.

74. Paragraph 74 contains a legal conclusion to which no response is required.

75. As to the allegations in paragraph 75, the regulations and statute cited speak for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory or statutory language.

76. As to the allegations in paragraph 76, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

77. As to the allegations in paragraph 77, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

78. Mr. Griffith denies the allegations contained in paragraph 78.

79. Paragraph 79 contains a legal conclusion to which no response is required.

#### **TENNESSEE LAW GOVERNING PHARMACIES**

80. As to the allegations in paragraph 80, the statute cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the statutory language.

81. As to the allegations in paragraph 81, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language.

82. As to the allegations in paragraph 82, the regulation cited speaks for itself, and Mr. Griffith denies any allegation not consistent with the regulatory language.

83. As to the allegations in paragraph 83, the regulations and statutes cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory or statutory language. Paragraph 83 further contains a legal conclusion to which no response is required. Mr. Griffith further affirmatively denies that he has violated any statute or regulation and that he has any duty, as is alleged in paragraph 83.

84. Mr. Griffith admits the allegations contained in paragraph 84.

#### **TENNESSEE LAW GOVERNING SPECIALLY REGULATED AREAS**

85. As to the allegations in paragraph 85, the regulations cited speaks for themselves, and Mr. Griffith denies any allegation not consistent with the regulatory language. Mr. Griffith further affirmatively denies that the regulations cited apply in any manner to pharmacists.

#### **Unlawfulness of a Prescription Is Material to Medicare Payment**

86. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 86 and thus denies the allegations.

87. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 87 and thus denies the allegations. Mr. Griffith further states that the articles cited in paragraph 87 speak for themselves, and Mr. Griffith denies any allegation not consistent with the language of the articles.

88. The first sentence of paragraph 88 contains a legal conclusion to which no response is required. Mr. Griffith denies the allegations contained in the second sentence of paragraph 88.

#### **DEFENDANTS' REGULATORY HISTORY**

##### ***Dale Hollow Pharmacy***

89. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 89 and thus denies the allegations.

90. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 90 and thus denies the allegations.

91. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 91 and thus denies the allegations.

92. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 92 and thus denies the allegations.

93. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 93 and thus denies the allegations.

94. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 94 and thus denies the allegations.

95. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 95 and thus denies the allegations.

96. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 96 and thus denies the allegations.

97. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 97 and thus denies the allegations.

98. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 98 and thus denies the allegations.

99. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 99 and thus denies the allegations.

***Xpress Pharmacy***

100. Mr. Griffith admits that he completed treatment for opioid addiction after being disciplined related to taking hydrocodone while employed at a different pharmacy. He further

admits that he entered into an agreed resolution with the Tennessee Board of Pharmacy in which he agreed to and did complete a five-year term of probation. Mr. Griffith denies the remaining allegations contained in paragraph 100.

101. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 101 and thus denies the allegations. Mr. Griffith further denies the allegation that he has a derogatory regulatory history.

102. Mr. Griffith admits the allegations contained in the first sentence of paragraph 102. Mr. Griffith is without sufficient information to admit or deny the allegations contained in the second and third sentences of paragraph 102 and thus denies the allegations.

103. Mr. Griffith admits that the DEA conducted an on-site inspection of Xpress in August of 2018, but is without sufficient information to admit or deny the remaining allegations contained in paragraph 103 and thus denies those allegations.

104. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 104 and thus denies the allegations.

105. Mr. Griffith is without sufficient information to admit or deny the allegations contained in the first sentence of paragraph 105 and thus denies the allegations. Mr. Griffith denies that he stated that he had been addicted to alcohol but admits the remaining allegations contained in the second sentence of paragraph 105. Mr. Griffith admits the allegations contained in the third sentence of paragraph 105, upon information and belief.

#### **Defendants' Medicare Fraud Scheme**

106. Mr. Griffith admits the allegations contained in the first sentence of paragraph 106, upon information and belief. Mr. Griffith denies the allegations contained in the second sentence of paragraph 106.

107. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 107 and thus denies the allegations.

108. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 108 and thus denies the allegations.

109. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 109 and thus denies the allegations.

110. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 110 and thus denies the allegations.

111. Mr. Griffith denies the allegations contained in paragraph 111.

112. Mr. Griffith denies the allegations contained in paragraph 112.

#### **DEFENDANTS' UNLAWFUL CONDUCT**

113. Mr. Griffith denies the allegations contained in paragraph 113.

114. Mr. Griffith denies the allegations contained in paragraph 114.

115. Mr. Griffith denies the allegations contained in paragraph 115.

116. Mr. Griffith denies the allegations contained in paragraph 116.

#### ***Specific Examples of Unlawful Dispensing Conduct***

117. Mr. Griffith denies the allegations contained in paragraph 117.

118. As to the allegations in paragraph 118, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith admits the allegations contained in the second and third sentences of paragraph 118 and denies the remaining allegations for lack of information sufficient to admit or deny.

119. As to the allegations in paragraph 119, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith

states that the guidelines and labeling cited speak for themselves and denies any allegation inconsistent with the cited language. Mr. Griffith further denies the remaining allegations for lack of information sufficient to admit or deny.

120. As to the allegations in paragraph 120, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

121. As to the allegations in paragraph 121, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

122. As to the allegations in paragraph 122, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

123. As to the allegations in paragraph 123, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

124. As to the allegations in paragraph 124, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

125. As to the allegations in paragraph 125, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

126. As to the allegations in paragraph 126, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

127. As to the allegations in paragraph 127, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

128. As to the allegations in paragraph 128, no response is required from Mr. Griffith for allegations not directed at Mr. Griffith. To the extent a response would be required, Mr. Griffith denies the allegations for lack of information sufficient to admit or deny.

129. Mr. Griffith denies the allegations contained in the first and tenth sentences of paragraph 129, as they relate to him. Mr. Griffith is without sufficient information to admit or deny the allegations in the second, third, fourth, fifth, sixth, seventh, eighth, and ninth sentences of paragraph 129 and thus denies the allegations. Mr. Griffith further denies that he violated any laws in filling any prescriptions for any patient.

130. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 130 and thus denies the allegations. Mr. Griffith further denies that he violated any laws in filling any prescriptions for any patient.

131. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 131 and thus denies the allegations. Mr. Griffith further denies that he violated any laws in filling any prescriptions for any patient.

132. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 132 and thus denies the allegations. Mr. Griffith further denies that he violated any laws in filling any prescriptions for any patient.



133. Mr. Griffith denies the allegations contained in paragraph 133.

134. Mr. Griffith denies the allegations contained in paragraph 134.

135. Mr. Griffith is without sufficient information to admit or deny the allegations contained in paragraph 135 and thus denies the allegations.

136. Mr. Griffith denies the allegations contained in paragraph 136.

**COUNT I--INJUNCTION FOR VIOLATION OF 21 U.S.C. § 842**

137. Paragraph 137 requires no response.

138. Mr. Griffith denies the allegations contained in paragraph 138.

**COUNT II--FALSE OR FRAUDULENT CLAIMS  
TO MEDICARE IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)  
(previously 31 U.S.C. § 3729(a)(1) (1986))**

139. Paragraph 139 requires no response.

140. Mr. Griffith denies the allegations contained in paragraph 140.

**COUNT III--FALSE OR FRAUDULENT CLAIMS  
TO MEDICARE IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)  
(previously 31 U.S.C. § 3729(a)(1) (1986))**

141. Paragraph 141 requires no response.

142. Mr. Griffith denies the allegations contained in paragraph 142.

143. Mr. Griffith denies the allegations contained in paragraph 143 and specifically denies that he is liable to the United States for any amount of damages or penalties.

**PRAYER FOR RELIEF**

Mr. Griffith denies that the United States is entitled to any of the relief sought in the Prayer for Relief.

Mr. Griffith further denies any allegation from the Complaint that is not specifically admitted or denied above.

### **AFFIRMATIVE AND OTHER DEFENSES**

Having fully answered the Complaint, Mr. Griffith makes the following affirmative and other defenses to liability in this matter. In making these defenses, Mr. Griffith does not suggest that he has the burden of proof or persuasion as to any of them, or that the United States is in any way relieved of its burden to prove its claims and damages, if any.

1. The Complaint does not state a claim upon which relief can be granted.
2. The Complaint does not plead the fraud allegations with the required particularity.

*See* Fed. R. Civ. P. 9(b).

3. Some or all of the United States' claims are barred by statute of limitations found in 29 U.S.C. § 3731(b).

4. To the extent any claims brought by the United States are pursued under statutes subsequently found to be unconstitutional either in this proceeding or otherwise, the claims against Mr. Griffith should then be dismissed.

5. Mr. Griffith did not have the requisite knowledge of or involvement in any alleged misconduct or the alleged inaccuracy of any claim, statement, or record used, presented or caused to be presented to the federal government to support a claim against it under the Federal False Claims Act.

6. Mr. Griffith did not conspire with any Defendant or other third parties to engage in any misconduct or commit any fraud.

7. The prescriptions at issue were written by licensed independent physicians, who represented that the medications were reasonable and necessary for the patients. Mr. Griffith relied, as he is permitted to do, on such medical judgment, in filling the prescriptions. Even if the

physician's statement of medical judgment is later concluded by others to be inaccurate, such conclusion cannot subject Mr. Griffith to False Claims Act liability.

8. Any attempt by the United States to extrapolate any claims and/or damages over a population of patients, without unique and individualized proof, would violate Mr. Griffith's rights to procedural and substantive due process provided by the Fifth and Fourteenth Amendments to the United States Constitution.

9. Any claim for relief in the Complaint is barred, because any actions taken by Mr. Griffith were done in good faith, based on reasonably available information, and constitute lawful, proper, justified, and/or privileged conduct.

10. The United States has failed to allege facts sufficient to support a claim for attorneys' fees, costs, treble damages, or civil penalties.

11. Any damages sustained by the federal government were not caused by Mr. Griffith.

12. Any award of financial penalties or treble damages against Mr. Griffith would constitute an excessive fine in violation of Mr. Griffith's rights under the Eighth Amendment to the United States Constitution.

13. The United States' use of guidance materials and other material that does not have the force of law to attempt to establish that Mr. Griffith violated the False Claims Act violates Mr. Griffith's rights to procedural and substantive due process provided by the Fifth and Fourteenth Amendments to the United States Constitution, as well as current U.S. Department of Justice policy.

14. Because, at the time this Answer is filed, discovery has not been completed, Mr. Griffith reserves the right to assert any and all further, supplemental, or other defenses, including affirmative defenses, which become available during the course of discovery or trial.

15. Mr. Griffith adopts by reference, as if fully restated herein, any affirmative defenses offered by the other Defendants in this matter that would likewise provide relief to Mr. Griffith.

**WHEREFORE**, having fully answered, Mr. Griffith respectfully requests the following relief:

- A. That the action be dismissed with prejudice;
- B. That a jury try the issues presented in this matter;
- C. That he be awarded costs and fees in defending this action; and
- D. The award of any further relief, at law or equity, as is deemed appropriate.

Respectfully submitted,

/s/ L. Wells Trompeter  
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*Attorneys for Defendant Michael Griffith*

### **CERTIFICATE OF SERVICE**

I hereby certify that on March 13, 2019, I electronically filed and served with the Clerk of the Court using the CM/ECF system, if registered, upon the following. If not registered, a service copy was also served via First Class U.S. Mail, on March 13, 2019.

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